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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,005	08/21/2003	Martin A. Cheever	920010.448C10	2062

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1643

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/647,005

Applicant(s)

CHEEVER ET AL.

Examiner

Anne L. Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9,11,13 and 14 is/are rejected.
- 7) ☒ Claim(s) 2,3,8,10 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. Claims 1-14 are pending and examined on the merits.

#### ***Claim Rejections - 35 USC § 112***

8. Claims 1, 4-7, 9, 11, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides consisting of SEQ ID NO: 1, 2, 7, 9 and 15, does not reasonably provide enablement for peptides of SEQ ID NOS: 3-6, 8, 10, 20 and 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure does not contain an adequate examples or guidance to enable the use of peptides consisting of SEQ ID NOS: 3-6, 8, 10, 20 and 23.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The claimed inventions are drawn to peptides that the specification teaches are useful as T cell epitopes. The structure of the peptides was determined by an analysis of the Her-2/neu sequence to determine possible T cell epitopes. The specification teaches that peptides consisting of SEQ ID NOS: 1, 7, 9 and 15 bind to T cells. The prior art teaches that SEQ ID NOS: 2, 7 and 15 induce a lytic response in T cells. However, U.S. Patent 5,840,839 (issued

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Nov. 24, 1998) teaches that finding a peptide that binds to a MHC molecule and stimulates an immune response is not a trivial matter, and that despite the existence of methods for predicting theoretical T cell epitopes, success in finding a structure of T cell epitope is not readily predictable. In the '839 patent (col. 19-20, and Table 1), data is shown that illustrates that a series of theoretical T cell epitopes that were derived based on a binding motif of MHC molecule HLA-A31 did not elicit a T cell lytic response when they are tested. These results suggest that theoretically selected T cell binding motifs have to be tested experimentally in order to determine whether they are actually T cell epitopes or not. Therefore, while it appears that the exemplified peptides and the peptides taught in the art are useful in generating lytic T cells, the claimed inventions encompass peptides that have not been tested. Because post-filing date art teaches that finding T cell epitopes is unpredictable, it appears that one of skill in the art would have to practice undue experimentation to practice the broadly claimed inventions. The further experimentation would be undue experimentation because one would be testing to discover a use for the claimed peptides.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Ioannides (U.S. Patent 6,514,942; issued Feb. 4, 2003; filing date March 14, 1995).

The instant application is accord priority back to March 31, 1995 because the continuation-in-part applications, 08/106,112 and 08/03,644, do not provide support for the recitation “and up to four amino acid, from the Her-2/neu polypeptide (SEQ ID NO: 68) which amino acids are adjacent to the carboxyl terminus of the peptide, are added to the carboxyl terminus of the peptide with or without prior removal of the number of the amino acids from the carboxyl terminus equal to the number added”. Support is accorded (back to 08/106,112) for dependent claims 2-14, because these claims are drawn to peptide consisting of the listed amino acid sequence.

Ioannides teaches peptides that are the same as SEQ ID NOS: 1, 2, 3, 6, 7, 9, 10 and 15 of claim 1. Therefore, Ioannides teaches peptides that are the same as that claimed.

***Conclusion***

No claim is allowed. Claims 1, 4-7, 9, 11, 13 and 14 are rejected. Claims 2, 3, 8, 10 and 12 are objected to for depending from a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran

Patent Examiner

June 26, 2006



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER